

United States Senate

WASHINGTON, DC 20510

June 20, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Dear Mr. Administrator:

Nearly three years ago, major reforms to the Toxic Substances Control Act (TSCA) were enacted by a strong bipartisan majority of both Houses of Congress, in the form of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Those reforms were intended to address longstanding structural problems with the original 1976 law that were broadly agreed to have stymied the Environmental Protection Agency's (EPA) authority to ensure that chemicals in and entering commerce are safe for human health and the environment.

These problems included debilitating constraints on EPA's ability to obtain and require the development of sufficient information on chemicals; the lack of a mandate for EPA to review and make affirmative risk findings on new chemicals prior to allowing them onto the market; the limited authority and mandate TSCA gave EPA to review the safety of chemicals already in commerce and regulate those that present unreasonable risk; and EPA's inability to share much of the chemical information it obtains with the public, or in the case of information deemed confidential, to share such information with other levels of government and health and environmental professionals.

The Lautenberg Act made improvements to address each of these problems. Among the many changes:

- Section 4: enhanced EPA's information authorities by allowing EPA to issue orders to obtain information and removing the original law's requirement that EPA first show potential risk in order to require a company to test a chemical;
- Section 5: required EPA to make affirmative safety findings for each new chemical, taking into account reasonably foreseen as well as intended uses of the chemical and requiring EPA to issue binding orders on any new chemical that "may present an unreasonable risk" or lacked sufficient information for EPA to conduct a reasoned evaluation;
- Section 6: required EPA to establish a continuous "pipeline" process to prioritize existing chemicals in commerce; subject those deemed high-priority to robust risk evaluations that account for: the full lifecycle of the chemical; its intended, known and reasonably foreseen conditions of use; and its potential risks to all "potentially exposed or susceptible subpopulations" (including children and workers); and impose regulatory

restrictions on any chemical found to “present an unreasonable risk” that are sufficient to mitigate those risks; and

- Section 14: required companies to substantiate and EPA to review many claims for protection from disclosure of confidential business information (CBI) and where approved to provide that such protection generally expires after 10 years unless a claim is reasserted and reapproved; reiterated that health and safety studies and related information are not eligible for CBI protection, subject to two narrow exceptions; and expanded authorized access to CBI to other levels of government and certain health and environmental professionals.

Sadly, the implementation of the Lautenberg Act has deviated dramatically from Congress’ intent and the new law’s requirements. This letter describes some of the many serious problems with the actions taken by this Administration since January of 2017 – actions that have rendered the law’s implementation weaker than even before the 2016 reforms.

For each of several major sections of TSCA as amended by the Lautenberg Act, we describe what was intended under the law, and provide some examples of how EPA’s implementation has fallen short of or deviated from that intent. For each area of concern, we request EPA’s prompt responses to the questions identified.

Section 4: EPA’s failure to use its enhanced information authorities under TSCA

One of the areas of greatest bipartisan consensus in TSCA reform was the need to improve EPA’s ability to readily obtain more robust information on chemicals, including data on exposure pathways and extent of exposure. It is impossible to ensure the safety of chemicals and protect human health and the environment without having solid information about a chemical’s risks. That’s just common sense.

Under the 2016 reforms to TSCA, EPA can now readily acquire information where needed to review new chemicals or to prioritize or review the risks of a chemical already on the market. The law also makes clear that EPA can require the development of real-world exposure information.

Yet in the nearly 3 years since passage of TSCA reform, EPA has not once used these new authorities, and seems to be avoiding using them at all costs – even where there are critical information gaps. For example, in a recent draft risk evaluation for Pigment Violet 29, EPA relied exclusively on an unsupported guesstimate from a company representative for the level of workplace exposure to a chemical, rather than using its authority to require actual workplace monitoring.

1. Why has EPA failed to use its information authorities?
2. Is there a policy at the agency that discourages use of such authorities?

3. Is there a policy for determining when such authorities are to be used?
4. Please share any existing policies with the committee by the end of June 2019.
5. EPA received public comments on the first 10 chemicals it is reviewing under TSCA that identified serious information gaps. Yet EPA has already stated publicly that it does not intend to use these authorities for any of the first 10 chemicals. Please explain this decision.
 - a. Has EPA documented the basis for its decision not to rely on these authorities with respect to the first 10 chemicals?
 - b. If so, please provide documents related to this decision.
6. Has EPA considered using any of these information authorities when assessing a new chemical since passage of the Lautenberg Act?
 - a. If so, please provide any documentation related to those decisions.
 - b. If not, why EPA has not considered using its information authorities when assessing any of the approximately 2,500 new chemical submissions it has reviewed over this time period?
 - c. Has EPA requested or required—and received—any vertebrate animal or non/vertebrate or non-animal toxicity information?

The law's vertebrate animal testing provisions in no way limit EPA's testing authorities; they simply call for EPA to rely on methods not involving vertebrate animals where such methods can provide information of equivalent or better scientific quality and relevance than vertebrate animal tests.

7. Does EPA consider that the law in any manner constrains EPA's authority to request or require testing if the needed test is an animal test? If so, please indicate where such a constraint is stated in the law.
8. Has EPA requested or required the use of any tests, whether involving vertebrate animals or not, using its section 4 authorities since passage of the Lautenberg Act?
9. In order for the public to understand how EPA's use of its information authorities affects the information that EPA receives, when and how will EPA make publicly available any:
 - a. voluntary exposure and toxicity information it receives for new or existing chemicals,
 - b. any requests or requirements EPA issues regarding new or existing chemicals, and

- c. exposure or toxicity information it receives as a result of such requests or requirements?
10. EPA has stated that the agency intends to rely principally or entirely on voluntary submissions of information.
- a. Please describe any steps that the EPA has taken to that it obtains all reasonably available information through voluntary submissions.
 - b. Please describe any steps that the EPA has taken to ensure that all companies with relevant information choose to provide information.
 - c. Please describe any steps that the EPA has taken to ensure that companies do not choose not to provide information that is unfavorable to their chemicals or that they for some other reason do not wish to provide EPA or have be made public.
11. Does EPA have a written policy or procedure to prevent receiving only incomplete or biased information when relying solely on voluntary submissions? If so, please provide them.

Section 5, part 1: EPA's failure to protect workers when reviewing new chemicals under TSCA

Congress gave EPA authority to regulate chemicals that may present risks to workers when TSCA was first enacted in 1976. Bipartisan TSCA reform in 2016 *strengthened* this authority by explicitly naming workers as a “potentially exposed or susceptible subpopulation” and requiring that EPA consider and address potential risks to workers when assessing new or existing chemicals.

Every year, industry submits 1,000 or so new chemical notices that EPA must review before the chemicals can enter the market. As part of this review, Congress told EPA to determine whether any of these chemicals “may present an unreasonable risk” to workers, using TSCA’s health standard, which is much more stringent than the Occupational Safety and Health Administration’s (OSHA) workplace standards. Where potential risks to workers are identified under TSCA, EPA must mitigate or eliminate those risks.

Unfortunately, EPA is failing to carry out the law and is putting the health of American workers in jeopardy. Even where EPA finds a new chemical does or may present serious risks to workers, the agency is allowing that chemical onto the market without imposing any conditions to protect the workers. EPA’s only justification for this is that it simply “expects” that workers will protect themselves from harmful workplace exposures by wearing personal protective equipment (PPE) that the company is not required to provide or train workers to use properly. In

doing this, EPA is deferring to OSHA regulations that allow workers to be exposed to chemical risks that are a thousand or more times higher than are acceptable under TSCA.¹

12. Why is EPA failing to carry out its duty to ensure workers are protected under TSCA, and is instead deferring to the much weaker health standards and regulations of OSHA?
13. On what legal basis is EPA allowing, without any conditions or restrictions, new chemicals onto the market that may present risk to workers, when the law clearly requires EPA to regulate such chemicals?
 - a. What actual evidence does the agency have that American workers will be sufficiently protected once these chemicals are on the market?
14. Please promptly provide us with your new chemicals decision-making policies that set forth the legal basis for your decisions regarding worker safety, along with any evidence that workers are being sufficiently protected under your approach. If you lack any such written policies or evidence, please explain why EPA has consistently applied this approach to so many of its recent new chemicals decisions?

Section 5, part 2: EPA's failure to adequately identify and review "reasonably foreseen" conditions of use when reviewing new chemicals under TSCA

When reviewing a new chemical, EPA is directed by statute to examine the chemical under its "conditions of use," defined in TSCA as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." In the context of new chemicals, Congress's inclusion of a requirement for EPA to examine "reasonably foreseen" activities is particularly noteworthy. Where EPA determines that a new chemical "is not likely to present an unreasonable risk" and the notifying company commences manufacture, that chemical is then placed on the TSCA Inventory and other companies can make or use that chemical at will without any notification to or review by EPA. Such a chemical may be produced or used in amounts or in ways that the original company did not intend at the time it first notified EPA of the new chemical. The risks of these additional activities, in combination with those from the originally intended activities, could well increase to a point where EPA would find that the chemical "presents" or "may present" an unreasonable risk. Hence it is vital that EPA consider both intended and reasonably foreseen activities in its initial review.

Unfortunately, EPA has attempted to skirt this requirement for an integrated assessment of both intended and reasonably foreseen conditions of use in several ways that are contrary to what TSCA requires:

¹ According to an analysis conducted by the Environmental Defense Fund, since EPA embarked on its dangerous new approach, EPA has given a green light to more than 80% of new chemicals it has reviewed – letting them onto the market with no conditions whatsoever. For 70% of these new chemicals, EPA clearly identified potential risks to workers but imposed no restrictions.

- For most new chemicals EPA has reviewed in recent months, it simply asserts there are no such reasonably foreseen uses.
- For most of the small subset of such new chemicals where EPA does identify a reasonably foreseen use, it merely states without providing any analysis that it expects that use to present no greater risk than the intended use. By doing this, EPA not only fails to demonstrate that the reasonably foreseen use is not likely to present an unreasonable risk; it also fails to consider that the combination of use could present such a risk.
- For the remaining few new chemicals where EPA does identify a reasonably foreseen use and identifies some potential concern with that use, EPA has separately promulgated a Significant New Use Rule (SNUR) that requires a company to notify EPA prior to engaging in that reasonably foreseen use. However, in these SNURs, EPA has not made clear that it would assess the potential exposure and risks from that use in combination with the already approved intended uses as part of its review of any such notice.

None of these recent policy changes to EPA's examination of new chemicals' conditions of use has been made public or subject to a public comment opportunity. While certain aspects of the third case outlined above appear to mirror aspects of EPA's November 2017 "decision-making framework" that was subject to public comment, EPA has never responded to those public comments, and when a lawsuit challenged that earlier framework, EPA did not apply the framework until the lawsuit was dismissed, apparently to evade judicial review of the framework.

15. Why has EPA implemented these new "reasonably foreseen" policies for months now without publicly describing them and allowing the public an opportunity to comment on them?
16. We expect that EPA has put its new policies and procedures in writing for internal use. Please provide us with copies. If written copies are not available, please explain how EPA is making decisions concerning new chemicals without such written policies.
17. What are EPA's plans to publish and take public comment on its current decision-making framework, including the legal and scientific justifications for it?
18. On what statutory basis does EPA believe it has authority to separate its consideration of potential risks arising from intended vs. reasonably foreseen conditions of use of a new chemical, given TSCA's clear mandate that they be assessed together?

Section 6: EPA's failure to assess even known conditions of use and pathways of exposure in conducting risk evaluations of existing chemicals under TSCA

The 2016 reforms to TSCA strengthened EPA's authority and mandate to conduct comprehensive, robust evaluations of potential risks posed by chemicals in commerce. As

mentioned above, EPA is required to determine whether a chemical substance, as a whole, presents an unreasonable risk under its conditions of use. To do so, EPA must evaluate potential risks arising from activities across the entire lifecycle of a chemical, and it must consider all “known” and “reasonably foreseen” circumstances, not just those “intended” by a company making or using a chemical.

Yet EPA has sought in numerous ways to limit the scope of its risk evaluations and risk determinations. First, in its final Risk Evaluation Rule,² EPA reversed course from its proposed rule and asserted sweeping authority to pick and choose what activities and what exposures it includes in its risk evaluation of a chemical. EPA claimed it could ignore any exposure to a chemical that also falls under the authority of another agency, such as OSHA, regardless of whether that agency has actually taken any action to mitigate the risks of the chemical. EPA also stated that it will exclude what it called “legacy” activities associated with a chemical. Even when a chemical is still being used or disposed of, EPA asserted that it could ignore exposures from those “legacy” activities if a chemical was not being actively manufactured for those uses. For example, EPA will ignore known exposures to: flame retardants that have been voluntarily phased out but are still present in millions of items of furniture still in active use; and to asbestos in insulation that remains in place in millions of homes, schools and other buildings. EPA will not only be ignoring exposures that clearly contribute to ongoing risks, it will do so even where no law or regulation prevents companies from resuming production of a chemical that has been voluntarily phased out.

But EPA has not stopped there. It has already begun to conduct risk evaluations that exclude most or all pathways of exposure to a chemical that fall under the jurisdiction of another statute that EPA administers. This means EPA will not account for the human health or environmental risks of releases and exposures to chemicals in air, surface, ground or drinking water, or wastes, no matter how they are disposed of. Not only will EPA ignore the contribution to overall exposure of environmental releases that are actually regulated under another law; it will also do so when no regulation has been issued at all for a chemical under another law—merely because EPA could in principle regulate the chemical in the future. The magnitude of the exposures EPA is zeroing out of its risk evaluations is enormous. For just seven of the first 10 chemicals undergoing risk evaluations under TSCA, EPA’s own data indicate that 66 million pounds are released every year to the air, water and land – even *after* accounting for any regulations of these chemicals in place under another law.

Finally, while TSCA requires EPA to determine whether a chemical as a whole, not individual uses of a chemical, poses an unreasonable risk, EPA has asserted that it can make use-by-use determinations of no unreasonable risk, without ever considering the combined exposures from multiple uses of the same chemical.

All of these assertions of authority are contrary to both the letter and the spirit of reformed TSCA, which was intended to ensure that EPA’s chemical risk assessments accounted for

² EPA-HQ-OPPT-2016-0654-0108

chemical exposures in the real world, where people are exposed to chemicals at work and at home, and through air, water and food as well as through the use of products.

19. How does EPA's exclusion of known uses and exposures to chemicals represent use of the "best available science," as required under TSCA section 26(h)?
20. How is EPA complying with TSCA section 26(k)'s requirement that EPA consider all reasonably available information when EPA ignores known uses and exposures to chemicals?
21. Please identify the specific language in TSCA that authorizes EPA to make risk determinations on individual uses of a chemical, rather than on the chemical as a whole, thereby not accounting for the potential for people or the environment to be exposed to a chemical in multiple ways.
22. Please identify the specific language in TSCA that authorizes EPA not to account for exposures from use or disposal of a chemical where that chemical is not currently manufactured for such a use.
23. How will EPA ensure that it meets its obligation under TSCA to protect against unreasonable risk, including risk to vulnerable subpopulations, if it defers to other agencies or EPA-administered statutes that use health standards that differ significantly from TSCA's and do not require protection of vulnerable subpopulations?
24. While EPA has announced these policies in its final framework rule and risk evaluation scopes and problem formulations, EPA has provided relatively little explanation of the legal basis for these approaches. Does EPA have a more robust legal analysis justifying these approaches? If so, please provide it/them.

Section 14: EPA's failure to provide timely public access to non-confidential information and access by eligible parties to confidential business information under TSCA

A key aim of TSCA even as originally enacted in 1976 was to ensure there is adequate information available on the potential health and environmental effects of chemicals. Congress clearly identified this aim in the first item articulated in TSCA's policy section 2(b)(1). TSCA also called on EPA to play a central role in providing broad access to such information on chemicals, while protecting legitimate confidential business information (CBI). Both roles are specified in TSCA section 14.

The 2016 TSCA amendments made major changes to section 14, enhancing requirements for companies' assertion and substantiation, and EPA's review, of CBI claims; for providing public access to chemical information; and for providing expanded access to CBI:

- CBI claims must be asserted at the time information is submitted to EPA. Except for certain specific types of information, all CBI claims must also be substantiated at that time.
- Health and safety studies and their underlying information are not eligible for CBI protection, subject to two narrow exceptions.
- EPA must review all CBI claims made to protect a chemical's identity, and at least 25% of all other types of CBI claims, except for those specifically exempted from substantiation. EPA must conduct its review and make a determination on each CBI claim within 90 days of its receipt. Any claim approved expires after 10 years unless reasserted and reviewed and approved by EPA.
- A public "unique identifier" must be assigned to any confidential chemical identity and used to "tag" all other information EPA has or receives on that chemical.
- Subject to certain conditions, EPA is to provide access to CBI by state, local and tribal governments, associated health and environmental professionals, medical personnel and first responders.
- EPA is to establish a "request and notification system" to provide "expedient and swift access" to CBI by government-associated health and environmental professionals, medical personnel and first responders.

These provisions of amended TSCA were immediately effective. Yet nearly three years after enactment, there is little evidence that EPA is effectively implementing these provisions or requiring compliance with them. Foremost among our concerns is EPA's failure to provide any means for the public to know about and have confidence in the extent of EPA CBI reviews, the determinations being reached, and the provision of access to information the law requires be provided. Some specific examples are listed below:

- EPA has provided no public accounting of how many CBI claims it has received and for what types of information; how many claims it has reviewed and within what timeframe; or the outcomes of any of the claim reviews it has conducted.
- While section 26(j) of TSCA requires EPA to make all of its determinations public, EPA has yet to do so for even a single CBI claim determination.
- Last December, EPA for the first time published a list of "unique identifiers" it had assigned to chemicals for the identities of which it had approved CBI claims. The list contained only 157 entries, and the most recent assignment dated back to August 2017, more than 18 months ago. Yet EPA has allowed the identities of hundreds of additional chemicals to be hidden from the public without assigning a unique identifier. For example, as of the end of January of this year, EPA had failed to assign a unique identifier to at least 270 new chemicals that have commenced manufacture and that are identified only by a generic name indicating EPA has allowed the specific name to be kept confidential.

- EPA appears to have made no progress at all toward establishing the “request and notification system” required under TSCA section 14(g)(3). That system is vital to ensuring that government-associated health and environmental professionals, medical personnel and first responders can gain access to confidential information they need to do their jobs.

Meanwhile, EPA has withheld health and safety studies or their underlying information from the public pertaining to the first chemical subject to a risk evaluation under TSCA, called Pigment Violet 29. Initially EPA erroneously asserted that such information was eligible for CBI protection under TSCA and was being withheld from the public on that basis. When that argument was rebutted, EPA acknowledged it had erred – but then came up with a different legal theory for withholding information that Congress clearly intended be publicly accessible.

Stakeholders report that when they have raised concerns about many of these issues to EPA staff, they have repeatedly been told that the agency does not have sufficient resources to carry out its duties under section 14. Yet comments received by the agency on its proposed user fee rule pointed to EPA’s severe underestimation of its costs for implementing these requirements of amended TSCA and urged EPA both to provide a fuller accounting of its expenses and to increase the amount of fees it was to collect to help offset these costs. Despite these concerns being voiced, EPA made no changes either to its cost estimate or to its fee structure.

25. When can we expect to see real progress in the agency’s meeting its duties under TSCA section 14? Specifically:
 - a. When will EPA provide a public accounting of how many CBI claims it has received and for what types of information; how many claims it has reviewed and within what timeframe; and the outcomes of (i.e., determinations on) the claim reviews it has conducted, as required?
 - b. When will EPA make public a current and complete list of “unique identifiers” for chemical identities for which EPA has approved CBI claims, which are essential for the public to identify other information EPA has on those chemicals?
 - c. When will government-associated health and environmental professionals, medical personnel and first responders be able to access the confidential information they need to do their jobs through the “request and notification system” for CBI access required under TSCA?
 - d. When will EPA make public health and safety studies and associated information on chemicals, which are not eligible for protection as CBI under TSCA?

Each of us contributed a great deal of time and energy into the Congressional reform process of TSCA with a wide variety of stakeholders from the environmental, health and business sectors. We all had the goal of restoring public trust in the federal government’s ability to protect the

public from hazardous chemicals in commerce. Three years later, we are sorely disappointed with the direction the Administration has taken this landmark bipartisan law. Your response to these questions in a timely manner would be appreciated so we can begin the process of turning implementation of the new TSCA in the right direction.

Respectfully,



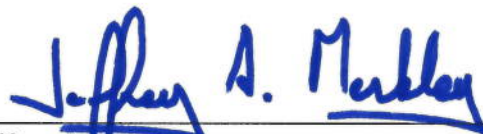
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